

#6 ADS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re patent application of:

Douglas A. RUSSELL et al..

Serial No. 09/824,200

Group Art Unit: 1655

Filed: 3 April 2001

Examiner: Unassigned

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TECH CENTER 1600/2900

For: EXPRESSION AND PURIFICATION OF BIOACTIVE, AUTHENTIC
POLYPEPTIDES FROM PLANTS

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.56(b)**

Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith on modified Form PTO-1449 is a listing of a documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. § 1.56. A copy of each listed document is being submitted to comply with the provisions of 37 C.F.R. § 1.97-1.98.

The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a prima facie prior art reference against the claims of the present application.

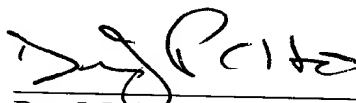
Applicants respectfully request that the listed documents be considered by the Examiner and formally be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with M.P.E.P. § 609.

The documents listed on the attached PTO-1449 were cited during the prosecution of the corresponding International Application. A copy of the International Search Report is attached. Four references cited in the International Search Report have been submitted to the U. S. Patent & Trademark Office in a subsequent Information Disclosure Statement filed 29 August 2001. Copies of these references are not being submitted.

The listed documents are being submitted in compliance with 37 C.F.R. § 1.97(b), prior to the mailing date of the first official action and within three months of the mailing date of the International Search Report. Accordingly, no fee is required in connection with this filing. Nonetheless, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1067.

Respectfully submitted,

31 May 2002



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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/10765

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N15/82 C12N15/62 C07K14/52 C07K14/535 C07K14/60
A01H5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12N C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal, BIOSIS, CAB Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 03012 A (CALGENE LLC (US)) 20 January 2000 (2000-01-20) page 2, line 15 -page 5, line 19 page 8, line 28 -page 10, line 30 page 14, line 26 -page 16, line 30 page 22, line 17 -page 23, line 25 example 4	1-6, 9-12, 14-16, 20, 21, 23, 26-29, 31-33, 40-47, 50, 51, 54-57, 59-61, 68-81, 90-92
Y	-/--	82-89

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

15 March 2002

Date of mailing of the international search report

22/03/2002

Name and mailing address of the ISA

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Authorized officer

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/10765

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	---- WO 98 10062 A (MONSANTO CO) 12 March 1998 (1998-03-12) cited in the application the whole document	82-89
A	---- WO 93 19189 A (MONSANTO CO) 30 September 1993 (1993-09-30) page 2, line 16 - line 27	87
A	---- US 5 723 755 A (FORTIN MARC G) 3 March 1998 (1998-03-03) page 2, line 57 -page 4, line 26	1-92
A	---- STAUB J M ET AL: "HIGH-YIELD PRODUCTION OF A HUMAN THERAPEUTIC PROTEIN IN TOBACCO CHLOROPLASTS" NATURE BIOTECHNOLOGY, NATURE PUBLISHING, US, vol. 18, no. 3, 2000, pages 333-338, XP000887246 ISSN: 1087-0156 cited in the application the whole document	1-92
A	---- US 5 650 554 A (MOLONEY MAURICE) 22 July 1997 (1997-07-22) the whole document	17-19
A	---- WO 97 29200 A (INST PFLANZENGENETIK & KULTUR) 14 August 1997 (1997-08-14) the whole document -----	7,8

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1-92, all partially

Present claims 1-92 relate to a method for producing a cytokine, as well as plant host systems, chimeric nucleic acids, expression cassettes for use in this method, defined by reference to desirable characteristics or properties, namely i) cultivating under 'appropriate' conditions, ii) accumulation of the cytokine to a level greater than 1% of the total soluble protein, iii) the cytokines being free from amino acid modifications and iv) the cytokines being free of novel glycosylation. The claims cover all methods, plant host systems, chimeric nucleic acids and expression cassettes having these characteristics or properties, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such methods, plant host systems, chimeric nucleic acids and expression cassettes. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the methods, plant host systems, chimeric nucleic acids and expression cassettes by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the methods, plant host systems, chimeric nucleic acids and expression cassettes based on the plasmids pwrg 4803 and 4825 (see Figure 3), as these appear to be the only constructs fulfilling the above-mentioned characteristics.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/10765

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 1-92, all partially
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/10765

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0003012	A	20-01-2000	BR 9912019 A EP 1097211 A2 WO 0003012 A2	19-02-2002 09-05-2001 20-01-2000
WO 9810062	A	12-03-1998	AU 4173497 A WO 9810062 A1	26-03-1998 12-03-1998
WO 9319189	A	30-09-1993	US 5593874 A CA 2108000 A1 EP 0602193 A1 JP 6508040 T WO 9319189 A1 US 5424412 A US 5859347 A	14-01-1997 20-09-1993 22-06-1994 14-09-1994 30-09-1993 13-06-1995 12-01-1999
US 5723755	A	03-03-1998	WO 9909187 A1 AU 3936697 A	25-02-1999 08-03-1999
US 5650554	A	22-07-1997	AU 709141 B2 AU 4295096 A BR 9600006 A CA 2208751 A1 WO 9621029 A1 EP 0871749 A1 US 6288304 B1 US 5948682 A ZA 9510999 A WO 9321320 A1 WO 9320216 A1	19-08-1999 24-07-1996 21-01-1998 11-07-1996 11-07-1996 21-10-1998 11-09-2001 07-09-1999 13-07-1996 28-10-1993 14-10-1993
WO 9729200	A	14-08-1997	DE 19604588 A1 DE 19620804 A1 CA 2246242 A1 WO 9729200 A1 EP 0879293 A1 JP 2000504567 T	14-08-1997 27-11-1997 14-08-1997 14-08-1997 25-11-1998 18-04-2000

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